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EXAMINER	
RICCI, CRAIG D	

ART UNIT	PAPER NUMBER
1628	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/597,803	TRIDGETT ET AL.	
	Examiner	Art Unit	
	CRAIG RICCI	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-68* is/are pending in the application.

4a) Of the above claim(s) *37,40,41,43-46,50-57,61 and 63-66* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35,36,38,39,42,47-49,58-60,62,67 and 68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/29/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. The amendments filed 7/29/2009 were entered.

2. New claims 61 and 63-66 which are drawn to a non-elected species are withdrawn. Accordingly, claims 35-36, 38-39, 42, 47-49, 58-60, 62 and 67-68 are the subject of this Office Action.

Response to Arguments

3. Applicants' arguments, filed 7/29/2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. **Claims 58-60, 62 and 67-68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention**.

6. New claim 58 is drawn to the 3,11b–cis-dihydrotetrabenazine or salt thereof according to claim 35 which consists of greater than 90% 3,11b–cis-dihydrotetrabenazine, or a salt thereof. It is unclear how 3,11b–cis-dihydrotetrabenazine can consist of less than 100% of 3,11b–cis-dihydrotetrabenazine. Accordingly, instant claim 58 is rejected since the skilled artisan would

not be reasonably apprised of what constitutes 3,11b–cis-dihydrotetrabenazine consisting of, for example, 91% 3,11b–cis-dihydrotetrabenazine. The skilled artisan would not be able to ascertain the metes and bounds of the claim.

7. For the same reasons, new claims 59-60, 62 and 67-68 are rejected. It is unclear and one of ordinary skill in the art would not be able to ascertain the metes and bounds of a composition comprising 3,11b–cis-dihydrotetrabenazine or a salt thereof wherein said 3,11b–cis-dihydrotetrabenazine consists of less than 100% 3,11b–cis-dihydrotetrabenazine or a salt thereof.

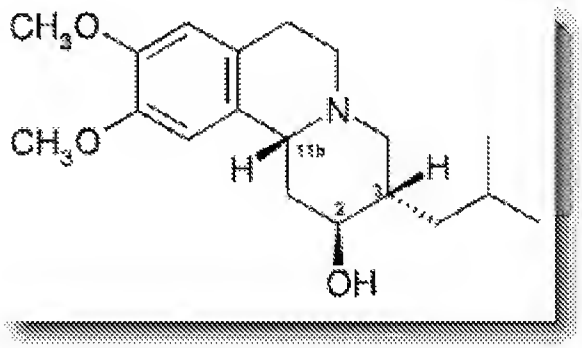
Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. **Claims 35, 42 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Kilbourn et al* (cited in a previous Action) as evidenced by *Williams et al* (cited in a previous Action)**.

11. As discussed in the previous Action mailed on 1/29/2009, instant claim 35 is drawn to 3,11b-*cis*-dihydrotetrabenazine or a salt thereof, more specifically in the form of a *2S*,3*S*,11b*R* isomer having the following formula  as elected by Applicant, which reads on claims 35 and 42. The elected compound species was rejected and that rejection is being reiterated in large part herein as follows:

12. Dihydrotetrabenazine is well known in the art and, as disclosed by *Kilbourn et al*, "contains three asymmetric carbon centers (C-2, C-3 and C-11b). The two isomers at the C-2 carbon can be easily resolved by column chromatography and are termed α- and β-dihydrotetrabenazine… For α- dihydrotetrabenazine, with two asymmetric centers, there are four possible isomers" (Page 249, Column 2). Accordingly, one of ordinary skill in the art would understand that β-dihydrotetrabenazine similarly contains two asymmetric centers and thus also has four possible isomers. As such, one of ordinary skill in the art would recognize that dihydrotetrabenazine has eight possible isomers which can be immediately envisaged as (1) *2S*,3*S*,11b*S*, (2) ***2S*,3*S*,11b*R***, (3) *2S*,3*R*,11b*S*, (4) *2S*,3*R*,11b*R*, (5) *2R*,3*S*,11b*S*, (6) *2R*,3*S*,11b*R*, (7) *2R*,3*R*,11b*S*, and (8) *2R*,3*R*,11b*R* (Applicant's elected species in bold). However, *Kilbourn et al* do not explicitly disclose Applicant's elected species.

13. As recognized by *In re Schauman*, 572 F.2d 312 (CCPA 1978), claims to a species (such as 3,11b-*cis*-dihydrotetrabenazine in the form of a *2S*,3*S*,11b*R* isomer) are anticipated where the

prior art teaches a genus embracing a limited number of members closely related to each other in structure and the properties possessed by the genus of the prior art is that disclosed for the claimed species. Significantly, a genus embracing about 20 compounds has been considered sufficiently limited such that each member of the genus can be at once envisaged. *In re Petering*, 301 F.2d 676 (CCPA 1962). In the instant case, the genus embraced by dihydrotetrabenazine comprises just eight members. Additionally, the properties of the genus taught by the prior art are those disclosed for the claimed species (i.e., inhibition of the human vesicular monoamine transporter isoform 2 (hVMAT2), see instant Specification, Page 1, Lines 15-16 and Page 4, Lines 22-23). Furthermore, it would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made to synthesize each of the eight member genus (including Applicants' elected species) in view of the following:

14. It is well known that a single isomer is often therapeutically superior to the racemic mixture and to the other isomers. The potential advantages include (1) improved therapeutic index through increased potency and selectivity and decreased side-effects; (2) improved onset and duration of effect; and (3) decreased propensity for drug-drug interactions. Indeed, as taught by *Williams et al*, discussing compounds that are combinations of isomers: "when introduced into an asymmetric, or chiral, environment, such as the human body, enantiomers will display different physical chemical properties producing significant differences in their pharmacokinetic and pharmacodynamic behavior. Such differences can result in adverse side effects or toxicity dues to one of the isomers or the isomers may exhibit significant differences in absorption, serum protein binding, and metabolism" (Page 50, Column 1). Accordingly, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to produce the

2S,3*S*,11b*R* isomer as recited by the instant claims. The skilled artisan would have predicted that the *2S*,3*S*,11b*R* isomer would likely possess properties similar to those exhibited by the racemic mixture and trans isomers disclosed by *Kilbourn et al*, and potentially superior properties as discussed above; thus, the skilled artisan would have been motivated to produce the *2S*,3*S*,11b*R* isomer in order to determine whether the *2S*,3*S*,11b*R* isomer does indeed exhibit superior properties (e.g., increased potency and selectivity, decreased side-effects, improved onset and duration, reduced drug-drug interactions, etc). "A known compound may suggest its analogs or isomers, either geometic isomers (cis v. trans) or position isomers (e.g., ortho v. para)" *In re Deuel*, 51 F.3d 1552, 34 USPQ 2d 1210, 1214 (Fed Cir 1995). Accordingly, instant claims 35 and 42 are rejected as *prima facie* obvious.

15. Applicants, however, traverse on a variety of grounds. First, Applicants assert that "no one of skill in the art could simply purify cis-dihydrotetrabenazine isomers from existing preparations of *trans*-dihydrotetrabenazine or tetrabenazine" (Applicant Argument, Page 13) and "no one knew how to make the *cis* isomers" (Applicant Argument, Page 15; see also Pages 16-17). However, Applicants are reminded that the arguments of counsel cannot take the place of evidence in the record. As such, Applicants' contention that no one of skill in the art could make the cis isomers must be supported by an appropriate affidavit or declaration. *In re Schulze*, 346 F.2d 600 (CCPA 1965). Applicants' reliance on *Kilbourn et al* does not demonstrate that "no one knew how to make the *cis* isomers" of dihydrotetrabenazine. Although *Kilbourn et al* indicate that studies of α- dihydrotetrabenazine have established the fixed relative configurations at C-3 and C11b, as noted by Applicants (Applicant Argument, Page 13), no where does *Kilbourn et al* indicate that "no one knew how to make the *cis* isomers" of dihydrotetrabenazine.

Applicants are advised to introduce by an appropriate affidavit or declaration evidence that one of skill in the art at the time the invention was made did, in fact, believe that the *cis* isomers could not be made. Accordingly, Applicants' arguments are not found persuasive.

16. Applicants also argue that *Williams et al* "provides only general information about isomers and discloses nothing whatsoever about any isomers of tetrabenazine or dihydrotetrabenazine" (Applicant Argument, Page 15). However, Applicants are reminded that one can not show nonobviousness by attacking references individually where the rejections are based on combinations of references. *In re Keller*, 642 F.2d 413 (CCPA 1981) and *In re Merck & Co.*, 800 F.2d 1091 (Fed. Cir. 1986).

17. Applicants next argue that the prior art provides no motivation for one of skill in the art to consider the compounds of the instant invention. Rather, Applicants contend that the prior art teaches away from the instant compounds (Applicant Argument, Pages 12 and 15). Applicants base this argument on the fact that *Kilbourn et al* indicate that studies of α- dihydrotetrabenazine have established the fixed relative configurations at C-3 and C11b. Yet, as noted by the court in *In re Fulton*, 391 F.3d 1195 (Fed. Cir. 2004), "[t]he prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit or otherwise discourage the solution claimed". Similarly, the fact that *Kilbourn et al* only identify certain members of the genus of isomers does not constitute a teaching away from the other members. Applicants also point to the fact that "the prior art has been entirely silent as to the existence of the 3,11b *cis*-isomers and methods for making the 3,11b *cis* isomers" as evidence that "no one was either motivated enough or capable enough to actually develop synthetic methods for making the 3,11b *cis*-isomers until Applicants

did so" (Applicant Argument, Pages 15-16). Yet, as clearly discussed above, whether or not someone actually synthesized the compound, motivation to do so existed. Accordingly, Applicants may be trying to assert secondary considerations such as a long felt but unsolved need, and failure of others as evidence of nonobviousness. Again, Applicants are advised to introduce by an appropriate affidavit or declaration evidence that "no one was either motivated enough or capable enough to actually develop synthetic methods for making the 3,11b *cis*-isomers until Applicants did so" to sufficiently indicate that there was a long felt but unsolved need, and failure of others to obtain to the instantly elected compound species.

18. Lastly, Applicants argue that the compounds of the instant invention have several unexpected properties, specifically a reduction in side effects including sedation (i.e., the instant compounds are non-sedating). While unexpected results can overcome a rejection based on obviousness, Applicants are reminded that the claims must be commensurate in scope with the asserted unexpected results. In the instant case, the claims (including the composition claims are not so limited. For example, as currently drafted, the composition claims embrace compositions comprising any amount of the elected species, although only specified amounts provided the allegedly unexpected results.

19. Accordingly, for all of the foregoing reasons, Applicants arguments are not considered persuasive. The rejection of claims 35 and 42 is maintained.

20. New claim 58 is drawn to the 3,11b–cis-dihydrotetrabenazine or salt thereof according to claim 35 which consists of greater than 90% 3,11b–cis-dihydrotetrabenazine, or a salt thereof. It is unclear how 3,11b–cis-dihydrotetrabenazine can consist of less than 100% of 3,11b–cis-dihydrotetrabenazine. Accordingly, instant claim 58 is also rejected.

21. **Claims 36, 38-39, 49, 59-60 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Kilbourn et al* (cited in a previous Action) as applied to claims 35 and 42 above, in view of *Reich et al* (cited in a previous Action).**

22. Instant claims 36 and 38-39 are drawn to compositions consisting of (claim 36) or comprising (claims 38-39) 3,11b–cis-dihydrotetrabenazine in substantially pure form (claim 36), being substantially free of 3,11b-trans-dihydrotetrabenazine (claim 38) or containing less than 5% of of 3,11b-trans-dihydrotetrabenazine (claim 39).

23. As discussed above, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to produce the cis isomer of dihydrotetrabenazine in an effort to identify a compound exhibiting desirable properties such as increased potency and selectivity, decreased side-effects, improved onset and duration, reduced drug-drug interactions, etc as compared to racemic dihydrotetrabenazine or other isomers of dihydrotetrabenazine. Furthermore, it would have been obvious to a person of ordinary skill in the art to formulate the compositions consisting of or comprising the cis isomer wherein the isomer is in substantially pure form as recited by instant claims 36 and 38-39. As disclosed by *Reich et al* (who teach compositions comprising amino-pyrazole compounds), "[a]s generally understood by those skilled in the art, an optically pure compound having one chiral center (i.e., one asymmetric carbon atom) is one that consists essentially of one of the two possible enantiomers (i.e., is enantiomerically pure), and an optically pure compound having more than one chiral center is one that is both diasteromerically pure and entiomerically pure" (Column 15, Line 62 - Column 16, Line 1). Moreover, *Reich et al* teach that compounds most preferably are used in a form that is at least 99% of a single isomer (98% entiomeric excess or diastereomeric excess) (Column 16,

Lines 7-8). As such, it would have been obvious to a person of ordinary skill in the art to formulate the composition consisting of or comprising the isomer in a substantially pure form (as recited by instant claim 36), being substantially free of the trans isomer (as recited by instant claims 38 and 39).

24. Applicants assert some of the same arguments as discussed above regarding claims 35 and 42 and which are not considered persuasive for the reasons discussed above. Additionally, Applicants argue that "Reich discloses nothing whatsoever about tetrabenazine or dihydrotetrabenazine" (Applicant Argument, Page 22). Yet, one can not show nonobviousness by attacking references individually where the rejections are based on combinations of references. *In re Keller*, 642 F.2d 413 (CCPA 1981) and *In re Merck & Co.*, 800 F.2d 1091 (Fed. Cir. 1986). In the instant case, the instant claims stand rejected over *Kilbourn et al* in view of *Reich et al*. Although, as discussed in the previous Action, *Reich et al* does not discuss the compounds of the instant invention, it is clear that the skilled artisan – who would be motivated to the make the instant isomers in view of *Kilbourn et al* and *Williams et al* – would in further view of *Reich et al* understand that isomers are preferably 99% pure. As such, the rejection of claims 36, 38-39 is maintained.

25. Instant claim 49 is drawn to a pharmaceutical composition comprising 3,11b-cis-dihydrotetrabenazine or a salt thereof and a pharmaceutically acceptable carrier. As discussed above, *Kilbourn et al* teach pharmaceutical compositions comprising a *trans* dihydrotetrabenazine isomer strongly binds VMAT2 (entire document). Accordingly, the skilled artisan would have been motivated to formulate pharmaceutical compositions comprising the *2S*,3*S*,11b*R* cis isomer to determine whether it can bind VMAT2 with increased potency and

selectivity, decreased side-effects, improved onset and duration, reduced drug-drug interactions, and so on. Additionally, although *Kilbourn et al* do not explicitly teach the inclusion of a pharmaceutically acceptable carrier, *Kilbourn et al* disclose that the pharmaceutical compositions "were injected via the tail vain" (Page 250, Column 2). Since it is unclear how an injectable composition could not include a pharmaceutically acceptable carrier, it is asserted that, absent evidence to the contrary, the composition of *Kilbourn et al* necessarily includes a pharmaceutically acceptable carrier.

26. Since Applicants do not offer any traversal as to the rejection of claim 49 beyond those already discussed, the rejection of claim 49 is maintained.

27. New claims 59-60 and 62 are drawn to a composition comprising 3,11b–cis-dihydrotetrabenazine and a pharmaceutically acceptable carrier, wherein the 3,11b–cis-dihydrotetrabenazine, or salt thereof, consists of greater than 90% 3,11b–cis-dihydrotetrabenazine, or a salt thereof. As discussed above, the prior art teaches compositions comprising 3,11b–cis-dihydrotetrabenazine and a pharmaceutically acceptable excipient. Additionally, it is unclear how 3,11b–cis-dihydrotetrabenazine can consist of less than 100% of 3,11b–cis-dihydrotetrabenazine. As such, the compositions comprising 3,11b–cis-dihydrotetrabenazine and a pharmaceutically acceptable carrier necessarily provide a composition wherein said 3,11b–cis-dihydrotetrabenazine, or a salt thereof, consists of greater than 90% 3,11b–cis-dihydrotetrabenazine, or a salt thereof. Accordingly, new claims 59-60 and 62 are rejected as *prima facie* obvious.

28. **Claims 47-48 and 67-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Kilbourn et al* (cited in a previous Action) as applied to claims 35 and 42 above in view of *Berge et al* (cited in a previous Action).**

29. Instant claims 47-48 are drawn to the compound of claim 35 in the form of an acid addition salt (claim 47), more specifically wherein the salt is a methane sulphonate salt (claim 48). As taught by *Berge et al*, "[t]he chemical, biological, physical, and economic characteristics of medicinal agents can be manipulated and, hence, often optimized by conversion to a salt form" (Page 1, Column 1). More specifically, *Berge et al* disclose that methanesulfonic acid is a potentially useful salt form of pharmaceutical agents (Page 5, Table III). Accordingly, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to formulate the isomer as a mesylate salt. The skilled artisan would have been motivated to do in order to optimize the chemical, biological, physical and economic characteristics of the compound in view of *Berge et al*.

30. Applicants traverse on the grounds that formulating salts of a compound is unpredictable in view of *Berge et al* (Applicant Argument, Page 24). Yet, as discussed by the court in *In re O'Farrell*, 853 F.2d 894 (Fed. Cir. 1988) obviousness does not require absolute predictability of success, only a reasonable expectation of success. Under the instant circumstances, an expectation of success would have been reasonable. That is, it would have been reasonable to expect that the instantly elected compound could be formulated as a methane sulphonate salt for inclusion in a composition, and it would have been obvious to try to do so with a reasonable expectation of success. Accordingly, Applicants' argument is not found persuasive.

31. New claims 67-68 are drawn to the composition of claims 59 and 67, respectively, In the form of an acid addition salt, more specifically a methane sulphonate salt. Thus, for the same reasons as discussed regarding instant claim 47-48, new claims 67-68 are also rejected.

Conclusion

The new ground(s) of rejection presented in this Office action are necessitated by Applicants' amendments to the claims. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CRAIG RICCI whose telephone number is (571) 270-5864. The examiner can normally be reached on Monday through Thursday, and every other Friday, 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on (571) 272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CRAIG RICCI/
Examiner, Art Unit 1628

/Brandon J Fetterolf/
Primary Examiner, Art Unit 1642